DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CEVH

#22

OCT 12 1990

Re: Ergamisol
Docket No. 90E-0266

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,584,305, filed by Johnson & Johnson under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Ergamisol, the human drug product claimed by the patent.

The total length of the review period for Ergamisol is 4,833 days. Of this time, 4,603 days occurred during the testing phase and 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 27, 1977.

   The applicant claims April 8, 1977, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 27, 1977, which was thirty days after FDA receipt of the IND application.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: November 1, 1989.

   FDA has verified the applicant's claim that NDA 20-035 was submitted on November 1, 1989.

3. The date the application was approved: June 18, 1990.

   FDA has verified the applicant's claim that NDA 20-035 was approved on June 18, 1990.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Robert L. Minier
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